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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

TRANSMITTAL OF LABELS AND CIRCULARS

(Part I - Submission Of Draft And Preliminary Proof Labeling)

LABEL REVIEW NO.: T2063005

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GENERAL INSTRUCTIONS

Type or print legibly in ink. Submit three copies of preliminary proofs and drafts. For revised labeling, indicate where changes have been made on the labeling copy. Assemble and staple each set, including attachments. The transmittal form must be dated and signed by the responsible head. Return both parts (*1 and 2*) of this form to the Food and Drug Administration, Center for Biologics Evaluation and Research (HFB-240), 8800 Rockville Pike, Bethesda, Maryland 20892.

MANUFACTURER'S NAME	Lederle Laboratories
NAME OF PRODUCT	Tetanus and Diphtheria Toxoids Adsorbed for Adult Use Aluminum Phosphate Adsorbed PUROGENATED®

LABELING

CHECK BELOW	TYPE SUBMITTED	REPLACE LABELING PREVIOUSLY REVIEWED: REVIEW NO	REPLACE LABELING PREVIOUSLY REVIEWED: DATED	MANUFACTURER'S IDENTIFICATION NO.	LABELING REPRESENTS CHANGE IN:
	A Container Label				☐ Dosage ☐ Manufacturing Method ☐ Contraindications, side effects, Precautions ☐ Arrangement ☐ Wording ☐ Other *(Specify)*
	B Package Label				
	C Circular				
	D Diluent				
x	E Other *(Specify)* comments	9022706	3/1/89	DX11, 23591	

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COMMENTS

Comments on FDA Draft Outline for circular requirements

RESPONSIBLE HEAD	SIGNATURE: D. K. McClintock DKMcClintock	DATE: JUN 23 1992

THE SPACE BELOW IS FOR REVIEW BY CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

COMMENTS: Please see comments in text of insert – please also reference DTP and DT circulars T2063006, T2063009 for applicable comments. Please submit a revised draft

REVIEWED BY	SIGNATURE	DATE
RETURNED BY	SIGNATURE: Amy Scott, Div. Product Certification, HFB-240, Metro Park North II, 295-8431	DATE: 7/27/92

FORM FDA 2567 (7/90) PREVIOUS EDITION MAY BE USED

200,000 cases reported in 1921 before the general use of diphtheria toxoid to only 15 cases reported from 1980 to 1983, the ratio of fatalities to attack rate has remained constant at about 5% to 10%.[4] The highest case fatality rates are in the very young and the elderly.

Immunization with Tetanus and Diphtheria Toxoids causes neutralizing antibodies to the toxins to be produced. Following adequate immunization with diphtheria toxoid, which induces antitoxin, it is thought that protection lasts for at least 10 years.[4] This significantly reduces both the risk of developing diphtheria and the severity of clinical illness. It does not, however, eliminate carriage of C. diphtheriae in the pharynx or on the skin.[4]

→ Please include a summary of the serologic data used to support efficacy.

INDICATIONS AND USAGE

Tetanus and Diphtheria Toxoids For Adult Use, aluminum phosphate - adsorbed PUROGENATED® (Td) is indicated for active immunization against tetanus and diphtheria in adults and children 7 years of age and older.[4,6]

Tetanus and Diphtheria Toxoids Adsorbed, PUROGENATED® is intended only for active immunization against tetanus and diphtheria, and is not to be used for treatment of actual infection.

Diphtheria and Tetanus Toxoids Adsorbed is recommended for active immunization of people younger than 7 years of age both for routine protection and as a preventive measure against diphtheria and tetanus, in circumstances in which the use of a combined triple vaccine containing pertussis antigen is contraindicated.

The Immunization Practices Advisory Committee (ACIP) of the U.S. Public Health Service recommends the use of the combined toxoids vaccine rather than single component vaccines for both primary and booster injections, including active tetanus immunization in wound management.[4]

Persons recovering from tetanus or diphtheria. Tetanus or diphtheria infection may not confer immunity; therefore, initiation or completion of active immunization is indicated at the time of recovery from these infections.[4]

Neonatal tetanus prevention. There is no evidence that tetanus and diphtheria toxoids are teratogenic. A previously unimmunized pregnant woman, who may deliver her child under

nonhygienic circumstances and/or surroundings, should receive two properly spaced doses of Td before delivery, preferably during the last two trimesters. Incompletely immunized pregnant women should complete the three-dose series. Those immunized more than 10 years previously should have a booster dose.[4] (See also pregnancy information under **PRECAUTIONS**).

If a contraindication to using tetanus toxoid-containing preparations exists in a person who has not completed a primary immunizing course of tetanus toxoid, and other than a clean minor wound is sustained, only passive immunization should be given using human Tetanus Immune Globulin (TIG). (see **DOSAGE AND ADMINISTRATION**).

— Include discussion of use with Diphtheria Antitoxin.

As with any vaccine, Tetanus and Diphtheria Toxoids Adsorbed, PUROGENATED® may not protect 100% of individuals receiving the vaccine.

CONTRAINDICATIONS

HYPERSENSITIVITY TO ANY COMPONENT OF THE VACCINE, INCLUDING THIMEROSAL, A MERCURY DERIVATIVE, IS A CONTRAINDICATION.

(THE OCCURRENCE OF ANY NEUROLOGICAL SYMPTOMS OR SIGNS FOLLOWING ADMINISTRATION OF THIS PRODUCT IS A CONTRAINDICATION TO FURTHER USE.) ?

IMMUNIZATION SHOULD BE DEFERRED DURING THE COURSE OF ANY FEBRILE ILLNESS OR ACUTE INFECTION. A MINOR AFEBRILE ILLNESS SUCH AS A MILD UPPER RESPIRTIORY INFECTION IS NOT USUALLY REASON TO DEFER IMMUNIZATION.[4]

with or without low grade fever (ACIP)

The clinical judgment of the attending physician should prevail at all times.

Routine immunization should be deferred during an outbreak of poliomyelitis, providing the patient has not sustained an injury that increases the risk of tetanus and providing an outbreak of diphtheria does not occur simultaneously.

Use of this or any vaccine ~~containing tetanus~~ vaccine is contraindicated if there has been any unacceptable adverse reaction to a previous dose of vaccine ~~containing tetanus~~ toxoid, including an anaphylactic reaction.

WARNINGS

THIS PRODUCT IS NOT RECOMMENDED FOR IMMUNIZING PERSONS LESS THAN 7 YEARS OF AGE. The concentration of diphtheria toxoid in preparations intended for use in persons 7 years of age of older is lower than that of the pediatric formulation (Diphtheria and Tetanus Toxoids Adsorbed, for pediatric use, [DT]): a lower dosage of diphtheria toxoid is recommended for persons 7 years of age or older because adverse reactions to the diphtheria

component are thought to be related to both dose and age.[4]

THE OCCURRENCE OF A NEUROLOGICAL OR SEVERE HYPERSENSITIVITY REACTION FOLLOWING A PREVIOUS DOSE IS A CONTRAINDICATION TO FURTHER USE OF THIS PRODUCT.[4] not needed in Warnings

THE ADMINISTRATION OF BOOSTER DOSES MORE FREQUENTLY THAN RECOMMENDED (see DOSAGE AND ADMINISTRATION) MAY BE ASSOCIATED WITH INCREASED INCIDENCE AND SEVERITY OF REACTIONS.[4]

→ every 10 years.

Persons who experience Arthus-type hypersensitivity reactions or temperature greater than 39.4°C (103°F), after a previous dose of tetanus toxoid usually have very high serum tetanus antitoxin levels and should not be given even emergency doses of Td more frequently than every 10 years, even if they have a wound that is neither clean nor minor.[4]

If a contraindication to using tetanus toxoid-containing preparations exists in a person who has not completed a primary immunizing course of tetanus toxoid, and other than a clean, minor wound is sustained, only passive immunization should be given using human Tetanus Immune Globulin (TIG).[4] Repetative from Indications & Usage

Td should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection unless the potential benefits clearly outweigh the risk of administration.

PRECAUTIONS

General

1. **THIS PRODUCT SHOULD BE USED FOR INDIVIDUALS 7 YEARS OF AGE OR OLDER.**
2. CARE IS TO BE TAKEN BY THE HEALTH CARE PROVIDER FOR THE SAFE AND EFFECTIVE USE OF THIS PRODUCT.
3. PRIOR TO ADMINISTRATION OF ANY DOSE OF Td, THE PARENT, GUARDIAN, OR ADULT PATIENT SHOULD BE ASKED ABOUT THE RECENT HEALTH STATUS AND IMMUNIZATION HISTORY OF THE PATIENT TO BE IMMUNIZED IN ORDER TO DETERMINE THE EXISTENCE OF ANY CONTRAINDICATION TO IMMUNIZATION WITH Td (SEE **CONTRAINDICATIONS, WARNINGS**).
4. WHEN THE PATIENT RETURNS FOR THE NEXT DOSE IN A SERIES, THE PARENT, GUARDIAN OR ADULT PATIENT SHOULD BE QUESTIONED CONCERNING OCCURRENCE OF ANY SYMPTOM AND/OR SIGN OF AN ADVERSE REACTION AFTER THE PREVIOUS DOSE (SEE **CONTRAINDICATIONS, ADVERSE REACTIONS**).

5. BEFORE THE INJECTION OF ANY BIOLOGICAL, THE ~~PHYSICIAN~~ health care provider SHOULD TAKE ALL PRECAUTIONS KNOWN FOR PREVENTION OF ALLERGIC OR ANY OTHER SIDE REACTIONS. This should include: a review of the patient's history regarding possible sensitivity; the ready availability of epinephrine 1:1,000 and other appropriate agents used for control of immediate allergic reactions; and a knowledge of the recent literature pertaining to use of the biological concerned, including the nature of side effects and adverse reactions that may follow its use.
6. Patients with impaired immune responsiveness, whether due to the use of immunosuppressive therapy (including irradiation, corticosteroids, antimetabolites, alkylating agents, and cytotoxic agents), a genetic defect, or other causes, may have a reduced antibody response to active immunization procedures.[5,6,7] Deferral of administration of DT may be considered in individuals receiving immunosuppressive therapy.[4,6] Other groups should generally receive this vaccine according to the usual recommended schedule.
7. This product is not contraindicated for use in individuals with Human Immunodeficiency Virus (HIV).
8. Special care should be taken to prevent injection into a blood vessel.

9. A separate sterile syringe and needle or a sterile disposable unit should be used for each individual patient to prevent transmission of hepatitis or other infectious agents from one person to another.

10. Shake vigorously before withdrawing each dose to resuspend the contents of the vial or syringe. — Dosage and Admin.

11. Needles should be disposed of properly and should not to be recapped.

12. NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 (AS AMENDED IN 1987)

This Act requires that the manufacturer and lot number of the vaccine administered be recorded by the health care provider in the vaccine recipient's permanent medical record, along with the date of administration of the vaccine and the name, address and title of the person administering the vaccine.

The Act further requires the health care provider to report to a health department of to the FDA the occurrence following immunization of any event set forth in the Vaccine Injury Table including: anaphylaxis or anaphylactic shock within 24 hours, encephalopathy or encephalitis within 7 days, residual seizure disorder, any acute complication or sequelae (including death) of above events, or any event that would contraindicate further doses of vaccine, according to this package insert.[9]

Information for Patients

Patients, parents or guardians should be instructed to report any serious adverse reactions to their health care provider.

The U.S. Department of Health and Human Services has established a new Vaccine Adverse Event Reporting system (VAERS) to accept all reports of suspected adverse events after the adminstration of any vaccine, including but not limited to the reporting of events required by the National Childhood Injury Act of 1986.[9] The VAERS toll free number for information is 800-822-~~7967~~ 7967 ←.

PRIOR TO ADMINISTRATION OF THIS VACCINE, HEALTH CARE PERSONNEL SHOULD INFORM THE PARENT, GUARDIAN, OR ADULT PATIENT OF THE BENEFITS AND RISKS OF VACCINATION AGAINST TETANUS AND DIPHTHERIA.

The health care provider should inform the parent or guardian of the importance of completing the immunization series and should provide the Vaccine Information ~~**Materials**~~ Pamphlets (~~VIMs~~ VIPs) **which are required to be given with each immunization.**

Drug Interactions

Children receiving immunosuppressive therapy may have a reduced response to active immunization procedures.

As with other intramuscular injections, tetanus and diphtheria toxoids should be given with caution to patients on anticoagulant therapy.

Tetanus Immune Globulin or Diphtheria Antitoxin, if used, should be given in a separate site with a separate needle and syringe.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Tetanus and Diphtheria Toxoids Adsorbed, PUROGENATED® has not been evaluated for its carcinogenic, mutagenic potential or for impairment of fertility.

Use in Pregnancy

Pregnancy Category C.

Animal reproductive studies have not been conducted with this product. There is no evidence that tetanus and diphtheria toxoids are teratogenic. Td should be given to inadequately immunized pregnant women because it affords protection against neonatal tetanus.[10] Waiting until the second trimester is a reasonable precaution to minimize any theoretical concern.[4] Maintenance of adequate immunization by routine boosters in non-pregnant women of childbearing age (see **DOSAGE AND ADMINISTRATION**) can obviate the need to vaccinate women during pregnancy.

Pediatric Use

The safety and effectiveness of Tetanus and Diphtheria Toxoids Adsorbed PUROGENATED® in children below the age of 6 weeks has not been established.

For either primary or booster immunization against tetanus and diphtheria in children less than 7 years of age, the use of Diphtheria and Tetanus Toxoids Adsorbed for Pediatric Use is recommended.

ADVERSE REACTIONS — Revise as per the suggested COSTART grouping and include all ADRs observed with any Td prod.t.

Local reactions, such as erythema, induration, and tenderness, are common after the administration of Td.[11-14] Such local reactions are usually self-limited and require no therapy. Nodule,[15] sterile abscess formation, or subcutaneous atrophy may occur at the site of injection. Systemic reactions such as fever, chill, myalgias, and headaches also may occur.[11-14]

Arthus-type hypersensitivity reactions, or high fever, may occur in persons who have very high serum antitoxin antibodies due to overly frequent injections of toxoid (See **WARNINGS**).

NEUROLOGICAL COMPLICATIONS,[16] SUCH AS CONVULSIONS,[17] ENCEPHALOPATHY,[17,18] AND VARIOUS MONO- AND POLYNEUROPATHIES[18-24] INCLUDING GUILLAIN-BARRE SYNDROME [25,26] HAVE BEEN REPORTED FOLLOWING ADMINISTRATION OF PREPARATIONS CONTAINING TETANUS AND/OR DIPHTHERIA ANTIGENS.

URTICARIA, ERYTHEMA MULTIFORME OR OTHER RASH, ARTHRALGIAS,[17] AND, MORE RARELY, A SEVERE ANAPHYLACTIC REACTION (I.E., URTICARIA WITH SWELLING OF THE MOUTH, DIFFICULTY BREATHING, HYPOTENSION, OR SHOCK) HAVE BEEN REPORTED FOLLOWING ADMINISTRATION OF PREPARATIONS CONTAINING TETANUS AND/OR DIPHTHERIA ANTIGENS.

DOSAGE AND ADMINISTRATION

For Intramuscular Use Only

Shake vigorously before withdrawing each dose to resuspend the contents of the vial or syringe. The vaccine should not be used if it cannot be resuspended.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. (See **DESCRIPTION.**)

The vaccine should be injected intramuscularly, preferably into the anterolateral aspect of the thigh or the deltoid muscle of the upper arm, with care to avoid major peripheral nerve trunks. Before injection, the skin at the injection site should be cleased and prepared with a suitable germicide.

After insertion of the needle, aspirate to help avoid inadvertent injection into a blood vessel.

Primary Immunization

The primary immunizing course for unimmunized individuals[9] 7 years of age or older consists of two doses of 0.5 ml each, 4 to 8 weeks apart, followed by a third (reinforcing) dose of 0.5 ml 6 to 12 months after the second dose. The reinforcing dose is an integral part of the primary immunizing course.[4]

Interruption of the recommended schedule with a delay between doses does not interfere with the final immunity achieved, nor does it necessitate starting the series over again, regardless of the length of time elapsed between doses.[4]

Children less than 7 years of age who remain incompletely immunized at an age greater than 7 years should be counted as having prior exposure to tetanus and diphtheria toxoids (e.g., a child who previously received 2 doses of DTP needs only 1 dose of Tetanus and Diphtheria Toxoids to complete the primary series for tetanus and diphtheria.)

The AAP and ACIP recommend that Td, HbOC, oral poliovirus vaccine (OPV), and/or measles-mumps-rubella (MMR) may be administered simultaneously (at separate sites) and result in seroconversion rates and rates of side effects similar to those observed when the vaccines are administered separately.[27,28,29]

see comment in DTP insert (refer to Haemophilus vaccines in general)

HbOC would not be normally administered simultaneously with Td due to recommended ages — Please Comment.

Booster Doses

A booster dose of 0.5 ml of Td is given 10 years after completion of primary immunization and every 10 years thereafter. If a dose is given sooner than 10 years, as part of wound management or on exposure to diphtheria, the next booster is not needed for 10 years thereafter. MORE FREQUENT BOOSTER DOSES ARE NOT INDICATED AND MAY BE ASSOCIATED WITH INCREASED INCIDENCE AND SEVERITY OF REACTIONS.[4] (See WARNINGS.)

Diphtheria Prophylaxis for Case Contacts

All case contacts, household and others, who have previously received fewer than three doses of diphtheria toxoid, should receive an immediate dose of an appropriate diphtheria toxoid-containing preparation and should complete the series according to schedule. Case contacts who have previously received three or more doses, but who have not received a dose of a preparation containing diphtheria toxoid within the previous five years, should receive a booster dose of a diphtheria toxoid-containing preparation appropriate for their age.[4] Td is an appropriate preparation in these circumstances for persons 7 years of age or older.

Tetanus Prophylaxis in Wound Management

The need for active immunization with a tetanus toxoid-containing preparation, with or without passive immunization with human Tetanus Immune Globulin (TIG) depends on both the condition of the wound and the patient's immunization history. Tetanus has rarely occurred among persons with a documented primary series of tetanus toxoid injections. A thorough attempt must be made to determine whether a patient has completed primary immunization.[4]

Individuals who have completed primary immunization against tetanus, and who sustain wounds which are minor and uncontaminated, should receive a booster dose of a tetanus toxoid preparation only if they have not received tetanus toxoid within the preceding 10 years. For other wounds, a booster is appropriate if the patient has not received tetanus toxoid within the preceding 5 years. Antitoxin antibodies develop rapidly in persons who have previously received at least two doses of tetanus toxoid.[4]

Individuals who have not completed primary immunization against tetanus, or whose immunization history is unknown or uncertain, should be immunized with a tetanus toxoid-containing product. Completion of primary immunization thereafter should be ensured. In addition, if these individuals have sustained a tetanus-prone wound, the use of human Tetanus Immune Globulin (TIG) is recommended. A separate syringe and site of administration should be used.[4]

SUMMARY GUIDE TO TETANUS PROPHYLAXIS IN ROUTINE WOUND MANAGEMENT[4]*

History of tetanus toxoid (doses)	Clean, minor wounds		All other wounds+	
	Td	TIG	Td	TIG
Unknown or <three	Yes	No	Yes	~~No~~ Yes
≥ three‖	No**	No	No++	No

* Important details are in the text.

\+ Such as, but not limited to, wounds contaminated with dirt feces, soil, saliva, etc.; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns and frostbite.

‖ If only three doses of fluid toxoid have been received, a fourth dose of toxoid, preferably an adsorbed toxoid, should be given.

** Yes, if more than 10 years since last dose.

++ Yes, if more than 5 years since last dose. (More frequent boosters are not needed and can accentuate side effects.)

Td is the preferred preparation for active tetanus immunization in wound management of patients 7 years of age or older. This is to enhance diphtheria protection, since a large proportion of adults are susceptible. Thus, by taking advantage of acute health care visits for wound management, some patients can be protected who otherwise would remain susceptible.[4]

HOW SUPPLIED

1875-31 5.0 ml vial

1875-47 10 (0.5 ml) LEDERJECT® Disposable Syringes

STORAGE

DO NOT FREEZE. STORE REFRIGERATED, AWAY FROM FREEZER COMPARTMENT, AT 2°C to 8°C (36°F to 46°F).

DIRECTIONS FOR USE OF LEDERJECT® DIPOSABLE SYRINGE

1. **Twist the plunger rod clockwise to be sure that rod is secured to rubber plunger base. SHAKE SYRINGE TO RESUSPEND CONTENTS.**

2. Hold needle shield in place with index finger and thumb of one hand while, with the other thumb, exert light pressure on plunger rod until the plunger base has been freed and demonstrates slight movement when pressure is applied.

3. Grasp the rubber needle shield at its base, twist and pull to remove.

4. To prevent needle-stick injuries, needles should not be recapped, purposely bent, or broken by hand.

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LEDERLE LABORATORIES DIVISION
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Pkg Insert/ TetDipAds